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TO: Commissioner John Auerbach and Members of the Public Health Council

THROUGH: Paul Dreyer, Ph.D., Director, Bureau of Health Care Safety and Quality

FROM: Grant Carrow, Ph.D., Deputy Director, Bureau of Health Care Safety and Quality

DATE: July 9, 2008

RE: Request for Final Promulgation of Amendments to Regulations at 105 CMR 700.000 concerning the Prescription Monitoring Program

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Introduction

The Drug Control Program (DCP) is returning to the Public Health Council to request final promulgation of amendments that would enhance the Massachusetts Prescription Monitoring Program (PMP). The proposed amendments were presented to the Council at its meeting of March 12, 2008 and a public hearing on the proposal was held on April 25, 2008. The purpose of the enhancements is to optimize use of the PMP for both public health and public safety through improving data quality, increasing data utility and utilization, reducing opportunities for drug diversion and facilitating interventions in drug addiction and abuse. Specifically, the amendments would:

1. Authorize the Department to provide dispensing information on Schedule II controlled substances to practitioners and pharmacies for clinical assessment and harm reduction;
2. Require pharmacies to report to the Department additional information about Schedule II prescriptions to increase utility of the database; and
3. Change the current customer identification provision from a request to a requirement that positive identification be presented before the dispensing of Schedule II drugs to reduce opportunities for prescription fraud.

While the amendments would facilitate the disclosure of information for the purpose of assisting a practitioner or pharmacy in assessing the possibility of abuse or diversion, they do not require or direct a practitioner or pharmacy to take any action that the practitioner or pharmacy believes to be contrary to the patient's best interests.

These amendments would enable implementation of a number of the recommendations in the Commonwealth's *Substance Abuse Strategic Plan* and are one of a number of steps the DCP is taking to enhance the PMP as part of federally-funded enhancement initiatives. The amendments are also consistent with recommendations of the Massachusetts OxyContin and

Other Drug Abuse Commission. While the amendments proposed here are not intended to address every possible area of regulatory enhancement of the PMP, they would provide the necessary foundation to enable the Program to reach its full potential to protect the public health and safety.

The final proposed amendments for promulgation are presented in Attachment A. A summary of issues raised in testimony and staff responses is presented in Attachment B.

Background

Prescription drug abuse is a critical public health and safety problem for Massachusetts and the nation. In a step to help address this problem, the Department, in 1992, established the PMP pursuant to joint regulations with the Board of Registration in Pharmacy. The program uses a computer-based, Electronic Data Transfer (EDT) system to collect prescribing and dispensing information on prescriptions for Schedule II drugs, which are those pharmaceuticals (narcotics, stimulants, sedatives) with the highest potential for abuse and are, consequently, among those most sought for illicit and inappropriate use.

The Department currently uses data from the system to determine prescribing and dispensing trends; provide educational information to health care providers; and provide case information to regulatory and law enforcement agencies concerning drug distribution and diversion. Medical Review Groups (MRGs), comprised of practitioners and pharmacists, provide peer review of the medical data and assist the Department in reviewing data for release to law enforcement and regulatory agencies. Since 1994, the MRGs have reviewed data related to over 1,980 cases, largely in response to requests from such agencies for information related to ongoing investigations. PMP data show that from 1993 to 2003, the number of prescriptions for all Schedule II opioids, including oxycodone products, increased 150% from 700,000 to 1.74 million. The PMP also has shown that the estimated number of individuals exhibiting drug seeking behavior ("doctor shopping") regarding Schedule II opioids increased 170% from FY 1996 (1,095 individuals) to FY 2007 (2,946 individuals).

Description of Final Proposed Amendments for Promulgation

Provision of Clinical Information

The amendments would enable the PMP to notify practitioners and pharmacies when a patient receives a controlled substance from more than one source and in quantities that the Commissioner determines to be harmful to the health of the patient (see M.G.L. c. 94C, §24). The amendments would require that protocols for disclosure of PMP data be established by the Department, in consultation with the Medical Review Group and the Prescription Monitoring Program Advisory Board, for appropriate identification of persons potentially engaged in diversion and in need of medical intervention. The practitioners and pharmacies who receive the information will be responsible for protecting the privacy of the information, as they are for all other medical information, in accordance with HIPAA (the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191).

The goal of this amendment is to enable the PMP to assist in identifying those at risk for or involved in prescription drug abuse and diversion, by providing medical practitioners with data on their patients, who then can be referred to appropriate treatment and/or interdiction. Data would be provided to practitioners only when potential problems are identified. This initiative would assist practitioners in preventing drug diversion and provide a tool for improving care for

their patients. The Department would implement this provision beginning with small-scale pilots with practitioners to identify the best practices for utilization of the system.

Reporting of Additional Data Fields

Department staff recommend further amendments to require reporting by pharmacies of additional prescription information, including patient identifying information such as name and address. Collection of these fields is a prerequisite to the implementation of M.G.L. c. 94C, §24 and the provision of data to practitioners about prescriptions for Schedule II drugs (see above) since the Department must be able to identify patients in the database. The patient information would be entirely confidential and could be disclosed only as provided in the regulations. All other PMPs in the country require reporting of patient data fields. Additional data fields included in the proposed amendments will also further enhance analysis and use of the PMP data, including enabling statistically valid epidemiological analysis of both the medical and non-medical use of Schedule II prescription drugs. The data fields that would be collected are recommended by the Alliance of States with Prescription Monitoring Programs, the National Association of State Controlled Substances Authorities and the federal National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER, P.L. 109-60).

Reporting of Customer Identification

Department staff further recommend amendments to strengthen the current requirements with respect to the reporting of customer identification. Current regulations only require the pharmacist to "make a good faith effort" to verify the ID of the person dropping off or picking up a prescription for a Schedule II drug. As a consequence of this language, some individuals seeking to divert prescription drugs are able to obtain Schedule II drugs without showing an ID. Even after enforcement efforts with pharmacies, 25% of prescription records in the database lack customer IDs, rendering a large portion unusable for identifying persons who may be engaged in unlawful diversion. The amendments would ensure that identification is obtained by pharmacies for each Schedule II prescription, either from the person dropping off or picking up the prescription. The revised requirement would help deter diversion of Schedule II drugs by ensuring that pharmacists consistently collect information about customers who obtain such controlled substances for themselves or on behalf of patients. Moreover, the requirement would ensure that the reports received by the PMP from pharmacies about the filling of Schedule II prescriptions contain more reliable information. The amendments would provide for exceptions to the requirement for positive identification to ensure that a patient will not be unreasonably denied access to needed medication simply by virtue of a customer not being able to present identification.

These proposed amendments would set forth the requirements for clinic and hospital outpatient pharmacies. The amendments do not apply to inpatients. The Board of Registration in Pharmacy would need to promulgate companion amendments to set forth the same requirements for community pharmacies.

Public Hearing

A public hearing was held on April 25, 2008 in Boston, MA and the hearing record was kept open through May 2, 2008. One individual presented oral and written testimony. Three organizations submitted written testimony during the public comment period. In addition, two state agencies have submitted written comments on the proposed regulations. Issues raised in

the testimony and comments as well as staff responses are summarized below and detailed further in Attachment B.

Dr. Carol Bates, MD and the Massachusetts Medical Society were generally supportive of the amendments but recommended broad access to the database by prescribers. Such an expansive program is beyond the scope of the current initiative. However, the proposed regulations would provide a necessary foundation on which such a program could be considered in the future.

The Massachusetts Pharmacists Association, Massachusetts Independent Pharmacists Association and National Association of Chain Drug Stores raised questions and concerns about a number of programmatic and operational details of implementation of the regulations (see Attachment B). Staff believe that these questions and concerns have already been addressed or will be addressed during implementation. To the extent that commenters recommended that programmatic and operational details be codified in regulations, staff do not believe that including such operational details in regulations is the best approach at this time. The regulations to date have not included these operational details. This has afforded DPH flexibility to respond programmatically to the rapid changes in health information technology and prevented locking pharmacies into using a particular technology. Unlike regulations, guidelines, policies and procedures may be amended at any time to respond to changing exigencies. As in the past, guidelines will be developed in consultation with the Prescription Monitoring Program Advisory Board, industry representatives and other interested parties. All programmatic and operational recommendations made in the testimony will be considered by DPH in the development of guidelines. The Department will provide a reasonable period of time after promulgation of the regulations for chain and other pharmacies to come into compliance with the requirements.

The Executive Office of Health and Human Services (EOHHS) recommended that the regulations be amended to permit release of PMP data, after MRG and DPH review and approval, to EOHHS for the purpose of identifying suspected fraud and abuse of the MassHealth program. The Department agrees with the recommendation and has amended the proposed regulation accordingly. The Department has and will continue to provide information on suspected cases of fraud and abuse of the MassHealth program, as already authorized by the regulation, to the Office of the Attorney General. In the future, the Department will work closely with both agencies in this regard.

The Attorney General recommended elimination of the requirement that the MRG review requests from law enforcement for PMP data. The Department is committed to working with the Attorney General to ensure that the PMP data is as assistive as possible. Nonetheless, this recommendation is beyond the scope of the current proposal. If a change in the MRG provision were considered desirable, after careful review and consultation, it would require development of a new regulatory proposal and a separate PHC review and public hearing process. The MRG and Department have worked with the Attorney General on policies to expedite responses to requests for information and are prepared to meet with the Attorney General, the PMP Advisory Board and other interested parties to ensure that all understand the role and functioning of the MRG, explore means by which the MRG process might be improved, and examine alternatives for addressing the expressed concerns. Staff recommend that, to enable the advances that would be realized with the current proposal, the regulatory amendments should be promulgated now, while the Attorney General's concerns are addressed separately.

As a final note, during the course of review of the proposed regulations, staff identified two areas requiring technical amendment. In 105 CMR 700.001, the definition for "Patient Identifier" needs to be deleted since, with these amendments, the term will no longer be used. In 105 CMR 700.006(J)(4)(c), the term "patients", which appears in the existing regulations, was inadvertently deleted from the proposed amendments and needs to be restored. These technical amendments as well as the accepted modification noted above have been made to the final proposed regulation that is presented in Attachment A.

Conclusion

Enhancement of the Massachusetts PMP is a prominent goal of the Commonwealth's *Substance Abuse Strategic Plan* and the report of the Massachusetts OxyContin and Other Drug Abuse Commission. In addition, DPH has been awarded federal grants to design and implement technological and other enhancements to the Program. Department staff believe that the regulatory amendments proposed here are critical to the success of these initiatives and to the ultimate goal of providing better data on use and misuse of Schedule II drugs. The amendments would better enable DPH to assist law enforcement and regulatory agencies in intervention with prescription fraud and other forms of drug diversion and to assist health care providers in detection and identification of individuals at risk for or involved in non-medical use of Schedule II pharmaceuticals. Staff have made technical changes to the proposal in response to some of the issues raised in the testimony. Therefore, staff request that the Public Health Council approve final promulgation of the amendments.

ATTACHMENT A

105 CMR 700.000: IMPLEMENTATION OF M.G.L. c. 94C

1. *Add the following:*

105 CMR 700.001: Definitions

Customer identifier means the identification number on a valid government issued identification, as specified by the Department, which a pharmacy obtains by inspecting the identification of the ultimate user or agent of the ultimate user to whom a prescription is dispensed.

2. *Delete the definition of "Patient Identifier".*

3. *Delete existing section 700.006(J) and insert the following:*

700.006: Requirements for Records, Inventories, and Reports

(J) Prescription Monitoring Program.
  (1) Pharmacy Reporting Requirements.
    (a) Every pharmacy located in a health facility registered with the Commissioner that dispenses controlled substances in Schedule II pursuant to a prescription shall, in accordance with standards established by the Department, transmit to the Department or its agent the following information for each such prescription:
      (1) pharmacy number;
      (2) pharmacy prescription number;
      (3) customer identifier, as defined in 105 CMR 700.001;
      (4) patient name;
      (5) patient address;
      (6) patient date of birth;
      (7) patient gender;
      (8) relationship of customer to patient;
      (9) national drug code (NDC) of controlled substance dispensed;
      (10) date prescription written by prescriber;
      (11) date the controlled substance is dispensed;
      (12) metric quantity of controlled substance dispensed;
      (13) estimated days supply of controlled substance dispensed;
      (14) prescriber's U.S. Drug Enforcement Administration (DEA) registration number; and
      (15) prescription coverage type.
    (b) 105 CMR 700.006(J) shall not apply to medication orders in hospitals.
    (c) A pharmacy that dispenses a Schedule II controlled substance in accordance with 105 CMR 701.004, but is unable to obtain and report the customer identifier required by 105 CMR 701.004, shall leave the customer identifier field blank or otherwise complete the field as directed by the Department.

(d) The information required by 105 CMR 700.006(J) shall be transmitted to the Department or its agent, in accordance with any procedures established by the Department, no later than 15 days following the last day of the month in which the prescription was dispensed by use of:
  (i) electronic device, including but not limited to computer diskette, compact disk, magnetic tape, or modem transmission in a format approved by the Department, or other acceptable electronic method approved by the Department; or
  (ii) Universal Claim Form or other form approved by the Department.

(e) Pharmacies reporting data from 25 or more prescriptions in any given month must provide the required information in accordance with 105 CMR 700.006(J)(1)(d)(i).

(2) Prescription Monitoring Program Advisory Board.

(a) The Commissioner of the Department of Public Health shall establish a Prescription Monitoring Program Advisory Board to assist in the implementation of 105 CMR 700.006(J) and any other related regulations. The membership of this Advisory Board shall include representatives of the Department of Public Health; Executive Office of Public Safety; disciplinary authorities, including the Boards of Registration in Medicine, Pharmacy, Dentistry, Podiatry, Veterinary Medicine, Nursing and Physician Assistants; representatives of associations or societies representing professions authorized to issue or dispense prescriptions, patient interests, and privacy interests; and a person with expertise in the design or operation of a secure automated data system.

(b) The Prescription Monitoring Program Advisory Board shall assist the Department in designing education programs for the proper use of Schedule II drugs.

(3) Prescription Monitoring Program Medical Review Group.

(a) The Commissioner shall establish Prescription Monitoring Program Medical Review Groups, to recommend accepted medical practice standards for the implementation of 105 CMR 700.006(J) and related regulations. The membership of each Medical Review Group shall consist of two or more registered practitioners, one of whom shall be affiliated with a health care facility, and at least one registered pharmacist. In all cases, members of the Medical Review Groups shall be registered health care practitioners and a majority shall be registered in the same discipline as the practitioner whose records are under review. Registered practitioners shall be designated by the Commissioner from lists approved by the appropriate Boards of Registration in the discipline under which records will be reviewed. Such lists shall be provided by the respective statewide professional societies, whose membership shall fully represent the complete geographic and practice differences represented in the state as a whole.
  (1) In the event that insufficient listings are available to comprise the appropriate membership of any particular Medical Review Group, the Commissioner may appoint additional members.
  (2) Whenever possible, the practitioners on a particular Medical Review Group shall be specialists, as designated by a national accrediting board acceptable to the Commissioner, in the same field as the practitioner whose records are being reviewed.

(3) In all cases, practitioners serving on the Medical Review Group must have a valid Controlled Substances Registration for prescribing Schedule II drugs, pursuant to M.G.L. c. 94C, § 18.

(b) The Medical Review Group shall assist the Department in the evaluation of prescription information.

(4) Privacy and Confidentiality.

(a) Except where otherwise provided by law or judicial order, the information collected pursuant to 105 CMR 700.006(J) shall not be disseminated by the Department to anyone other than:

(1) a duly authorized representative of the board or agency responsible for registration, regulation or discipline of practitioners authorized to prescribe or dispense Schedule II controlled substances acting in accordance with official duties;

(2) a law enforcement agency when acting in accordance with its official duties in conducting a bona fide criminal investigation or prosecution of criminal violations. Requests for inspection of these records shall first be directed to the Office of the Attorney General of Massachusetts, or the Massachusetts State Police Diversion Investigation Unit, or the United States Drug Enforcement Administration, for notification and approval prior to action by the Department;

(3) the Executive Office of Health and Human Services for the purpose of identifying suspected fraud or abuse of the MassHealth program;

(4) a practitioner, including a pharmacy, in accordance with 105 CMR 700.006(J)(4)(d); or

(5) an individual who is the data subject who has access to this data pursuant to a statute or regulation of the Commonwealth.

(b) All requests for information pursuant to 105 CMR 700.006(J)(4)(a)(1), (2) and (3) shall be in writing. All such information generated shall be reviewed and approved by the Commissioner or his or her designee and the Medical Review Group prior to release by the Department.

(c) In the event that the Department, through computer analysis and review of the records generated by the prescription monitoring program, finds patterns of prescribing or dispensing that raise questions regarding the activity of a patient, practitioner or pharmacy, the Department shall provide such information to the appropriate Medical Review Group for review and possible referral, as provided for in 105 CMR 700.006(J)(4)(a)(1), (2) and (3).

(d) Notwithstanding the provisions of 105 CMR 700.006(J)(4)(c), in order to prevent the diversion of Schedule II controlled substances and to identify persons who may be in need of treatment for drug abuse, the Commissioner or his or her designee may disclose to practitioners and pharmacies who have dispensed or are evaluating the dispensing of such controlled substances information concerning prior dispensing of such controlled substances to a patient or his or her agents.

(i) Such information may be disclosed only upon determination by the Commissioner or his or her designee that a patient is receiving a Schedule II controlled substance from more than one source and in quantities that he/she determines to be harmful

to the health of the patient or that disclosure otherwise is necessary to prevent the unlawful diversion of a Schedule II controlled substance.

(ii) Such disclosure shall be in conformance with protocols established by the Department, in consultation with the Medical Review Group and the Prescription Monitoring Program Advisory Board, concerning appropriate identification of persons potentially engaged in diversion and in need of medical intervention. The Medical Review Group shall as needed thereafter review the content and application of the protocols and make recommendations to the Department for improvement of the disclosure process. In undertaking such review, the Medical Review Group shall be provided upon request with all pertinent information as to disclosures made pursuant to this subsection.

(iii) Such disclosure may be at the initiation of the Department or in response to an inquiry by a practitioner. The disclosure shall be for the purpose of assisting the practitioner or pharmacy to assess the possibility of abuse or diversion, but shall not require or direct the practitioner to take action that the practitioner believes to be contrary to the patient's best interests.

105 CMR 701.000: REGULATIONS ADOPTED JOINTLY BY THE DEPARTMENT OF PUBLIC HEALTH AND THE BOARD OF REGISTRATION IN PHARMACY FOR THE IMPLEMENTATION OF M.G.L. c. 94C

4. *Add the following:*

105 CMR 701.004: Requirements for Positive Identification for Dispensing of a Controlled Substance in Schedule II.

(A) A pharmacy shall require that a customer identifier, as defined in 105 CMR 700.001, be presented by the ultimate user or agent of the ultimate user to whom a prescription for a controlled substance in Schedule II is dispensed.

(B) The requirement in 105 CMR 701.004(A) may be waived provided that:

(1) the pharmacy has reason to believe that the failure to dispense the controlled substance would result in a serious hardship for the ultimate user or agent of the ultimate user, and documents the reason; and

(2) the ultimate user or agent of the ultimate user prints his or her name and address on the reverse side of the prescription and signs his or her name thereto.

ATTACHMENT B

List of Testimony and Agency Commentary Provided or Submitted

Name of Organization or Individual	Format	Date Received
Attorney General	Written	June 11, 2008
Carol Bates, MD	Written and Oral	Apr. 25, 2008
Executive Office of Health and Human Services (EOHHS)	Written	Mar. 24, 2008
Massachusetts Medical Society (MMS)	Written	Apr. 22, 2008
Massachusetts Pharmacists Association (MPhA) and Massachusetts Independent Pharmacists Association (MIPA)	Written	Apr. 29, 2008
National Association of Chain Drug Stores (NACDS)	Written	Apr. 25, 2008

Analysis of Testimony and Agency Comments

Source: Attorney General
Comment: Recommend elimination of the requirement that the MRG review requests from law enforcement for PMP data.
Response: The Department is committed to working with the Attorney General to ensure that the PMP data is as assistive as possible. Nonetheless, this recommendation is beyond the scope of the current proposal. If a change in the MRG provision were considered desirable, after careful review and consultation, it would require development of a new regulatory proposal and a separate PHC review and public hearing process. The MRG and Department have worked with the Attorney General on policies to expedite responses to requests for information and are prepared to meet with the Attorney General, the PMP Advisory Board and other interested parties to ensure that all understand the role and functioning of the MRG, explore means by which the MRG process might be improved, and examine alternatives for addressing the expressed concerns.

Source: Attorney General
Comment: Recommend that the regulations include a provision that requires that PMP information be provided to law enforcement in the form in which it is received by DPH.
Response: In most cases, the Department and MRG have been able to work with law enforcement agencies to provide the information needed for investigations. As noted above, the Department will work with the Attorney General to determine whether there are ways to further improve the review and disclosure process while protecting patient privacy.

Source: Carol Bates, MD
Comment: I support a registry or database and urge in the strongest possible terms that this registry be designed to allow full access by prescribers to a complete data base of Schedule II patient dispensing history.
Response: A registry with full access by prescribers to the PMP database is beyond the scope of the proposed regulations. The amendments as currently proposed would provide a necessary foundation on which such a registry could be considered in the future.

Source: EOHHS
Comment: Recommend the regulations be amended to permit release of PMP data to the

Executive Office of Health and Human Services for the purpose of identifying suspected fraud and abuse of the MassHealth program.
Response: Department staff agree with the recommendation and has amended the proposed regulations accordingly. The Department has and will continue to provide information on suspected cases of fraud and abuse of the MassHealth program, as already authorized by the regulation, to the Office of the Attorney General. In the future, the Department will work closely with both agencies in this regard.

Source: MMS
Comment: The regulations do not provide details on how the Department intends to provide real time responses to inquiries from authorized individuals, including physicians.
Response: As noted above, a system of real time response to prescriber requests for information is beyond the scope of the proposed regulations. However, such a system could be considered in the future.

Source: MPhA and MIPA
Comment: Pharmacies must be given sufficient time to upgrade their computer programs prior to the deadline to provide the new information. Allowing at least 90 days after promulgation of the regulations will allow owners to upgrade their systems and learn to use the new system without fear of being penalized.
Response: The Department will provide a reasonable period of time after promulgation of the regulations for pharmacies to come into compliance.

Source: MPhA and MIPA
Comment: The regulations should specify a particular program, preferably the ASAP Telecommunications Format for Controlled Substance (2005 version) to be used from the date the regulations take effect, unless amended further by the regulatory review process.
Response: Department staff do not support any language that would tie the PMP and pharmacies to particular technologies that may become outdated. The regulations have not heretofore locked DPH or pharmacies into a particular transmission standard. The regulations as proposed would provide DPH with the flexibility to respond programmatically to rapid changes in health information technology. Guidelines may be amended more readily than regulations to respond to changing exigencies and this is of benefit to both DPH and the industry. Guidelines on the issues raised have been and will continue to be developed in consultation with the industry and other interested parties.

Source: NACDS
Comment: The Department should clarify that the pharmacy number be the pharmacy's Drug Enforcement Administration (DEA) registration number. Since all pharmacies must have a DEA number to dispense controlled substances prescriptions, this is the logical number to require as the pharmacy identifier.
Response: Pharmacies are already reporting the National Council on Prescription Drug Programs (NCPDP) number. Addition of the pharmacy DEA number involves a one-time software programming change to report an existing field. The Department's use of both the DEA number and the NCPDP number as dispenser identifiers is consistent with the recommendations of the Prescription Monitoring Program Standards Work Group convened by the National Association of State Controlled Substances Authorities in 2003. NACDS participated in the Work Group that developed the recommendations. The Department will need both the DEA and NCPDP numbers to assure a smooth transition from the older ASAP standard

to ASAP 2005. Department staff are not asking pharmacies to use the National Provider Identifier (NPI) number at this time but to have a placeholder for the NPI to facilitate expected use of that number as required by federal agencies.

Source: NACDS

Comment: The Department should change the field requirement "date the controlled substance is dispensed" to "date the controlled substance is filled." Prescriptions are not always picked up and dispensed to patients on the day that they are filled in the pharmacy. Thus, requiring a pharmacy to report the "date dispensed" would be operationally problematic because pharmacies enter prescription monitoring data into their computer systems as part of the general dispensing process.

Response: Department staff are not proposing to amend the current language. The regulations define dispense to include the packaging, labeling or compounding necessary for delivery of a controlled substance. Thus pharmacies may use the date the prescription is packaged, labeled or compounded, which staff understand is the current practice.

Source: NACDS

Comment: The Department should further amend the definition of "customer identifier" to specify that the customer's or patient's phone number could be collected as an alternative to a government issued ID. NACDS is concerned that a customer or patient may not have a proper ID or may have forgotten or lost it, thereby precluding their ability to obtain needed medication.

Response: A telephone number is not an ID number. The regulations already contain a provision to address these circumstances and to ensure that individuals are not precluded from obtaining needed medications due to lack of a proper customer ID.

Source: NACDS

Comment: NACDS supports submitting prescription monitoring program data in accordance with the standards set forth in the American Association for Automation in Pharmacy (ASAP) Telecommunications Format for Controlled Substances, 2005 version.

Response: The Department agrees to require use of ASAP Telecommunications Format for Controlled Substances, 2005 Version for pharmacy submission of all data elements to the Massachusetts Prescription Monitoring Program at this time, to facilitate implementation of the regulatory amendments, provided all elements required by the regulations can be reported. Department staff will continue to work with NACDS and other interested parties to examine possible use of the 2007 version of the ASAP standard in the future.